IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA

CHARLESTON DIVISION

KATHERINE L. HALL,

Plaintiff,

v. CIVIL ACTION NO. 2:12-cv-08186

BOSTON SCIENTIFIC CORPORATION,

Defendant.

MEMORANDUM OPINION AND ORDER
(Motions for Summary Judgment)

Pending before the court is Boston Scientific Corporation's Motion for Summary Judgment Against Plaintiff Katherine Hall ("Motion for Summary Judgment") [Docket 59] and the plaintiff's Motion for Partial Summary Judgment [Docket 61]. For the reasons explained below, the defendant's Motion for Summary Judgment [Docket 59] is **GRANTED in part** and **DENIED in part**, and the plaintiff's Motion for Partial Summary Judgment [Docket 61] is **GRANTED in part** and **DENIED as moot in part**.

I. Background

This case resides in one of seven MDLs assigned to me by the Judicial Panel on Multidistrict Litigation concerning the use of transvaginal surgical mesh to treat pelvic organ prolapse ("POP") and stress urinary incontinence ("SUI"). In the seven MDLs, there are more than 70,000 cases currently pending, approximately 15,000 of which are in the Boston Scientific Corporation ("BSC") MDL, MDL No. 2326. In this particular case, the plaintiff, Katherine Hall, was surgically implanted with the Obtryx Transobturator Mid-Urethral Sling System ("Obtryx"),

a mesh product manufactured by BSC to treat SUI. (*See* Second Am. Short Form Compl. [Docket 109], at ¶ 8). Ms. Hall received her surgery at Gundersen Lutheran Hospital in La Crosse, Wisconsin, on October 12, 2006. (Pl. Fact Sheet [Docket 59-2], at 6). She now claims that as a result of the implantation of the Obtryx, she has developed various complications, including mesh erosion, lower abdominal pain, pelvic pressure, burning sensations, and renewed SUI. (*See id.* at 7). The plaintiff advances the following claims against BSC: negligence; strict liability for design defect, manufacturing defect, and failure to warn; breach of express and implied warranties; and fraudulent concealment. (*See* Second Am. Short Form Compl. [Docket 109] ¶ 13). BSC moves for summary judgment on each of these claims, arguing that they lack evidentiary or legal support. The plaintiff also moves for summary judgment on BSC's affirmative defenses of federal preemption and the learned intermediary doctrine.

II. Legal Standard

A. Summary Judgment

To obtain summary judgment, the moving party must show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a). In considering a motion for summary judgment, the court will not "weigh the evidence and determine the truth of the matter." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 249 (1986). Instead, the court will draw any permissible inference from the underlying facts in the light most favorable to the nonmoving party. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587–88 (1986).

Although the court will view all underlying facts and inferences in the light most favorable to the nonmoving party, the nonmoving party nonetheless must offer some "concrete evidence from which a reasonable juror could return a verdict in his [or her] favor." *Anderson*,

477 U.S. at 256. Summary judgment is appropriate when the nonmoving party has the burden of proof on an essential element of his or her case and does not make, after adequate time for discovery, a showing sufficient to establish that element. *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-23 (1986). The nonmoving party must satisfy this burden of proof by offering more than a mere "scintilla of evidence" in support of his or her position. *Anderson*, 477 U.S. at 252. Likewise, conclusory allegations or unsupported speculation, without more, are insufficient to preclude the granting of a summary judgment motion. *See Felty v. Graves Humphreys Co.*, 818 F.2d 1126, 1128 (4th Cir. 1987); *Ross v. Comm'ns Satellite Corp.*, 759 F.2d 355, 365 (4th Cir. 1985), *abrogated on other grounds*, *Price Waterhouse v. Hopkins*, 490 U.S. 228 (1989).

B. Choice of Law

Under 28 U.S.C. § 1407, this court has authority to rule on pretrial motions in MDL cases such as this. The choice of law for these pretrial motions depends on whether they involve federal or state law:

> When analyzing questions of federal law, the transferee court should apply the law of the circuit in which it is located. When considering questions of state law, however, the transferee court must apply the state law that would have applied to the individual cases had they not been transferred for consolidation.

In re Temporomandibular Joint (TMJ) Implants Prods. Liab. Litig., 97 F.3d 1050, 1055 (8th Cir. 1996) (internal citations omitted). To determine the applicable state law for this motion based on the statute of limitations, I must turn to the choice-of-law rules of the jurisdiction where the plaintiff first filed her claim. *See In re Air Disaster at Ramstein Air Base, Ger.*, 81 F.3d 570, 576 (5th Cir. 1996) ("Where a transferee court presides over several diversity actions consolidated under the multidistrict rules, the choice of law rules of each jurisdiction in which the transferred actions were originally filed must be applied."); *In re Air Crash Disaster Near Chi., Ill.*, 644 F.2d 594, 610 (7th Cir. 1981); *In re Digitek Prods. Liab. Litig.*, MDL No. 2:08-

md-01968, 2010 WL 2102330, at *7 (S.D. W. Va. May 25, 2010). The plaintiff in this case originally filed her complaint in the U.S. District Court for the District of Minnesota, (*see* Compl. & Demand for Jury Trial [Docket 1], at 1), and accordingly, I must apply Minnesota's choice-of-law rules.

The parties agree, as does this court, that Minnesota's choice-of-law principles compel application of Wisconsin law to the plaintiff's product liability claims. Minnesota focuses on two factors in resolving choice-of-law issues: (1) the maintenance of interstate order and (2) the advancement of the forum state's interests. *See In re Baycol Prods. Litig.*, 218 F.R.D. 197, 207 (D. Minn. 2003) (stating that only two factors in Minnesota's usual five-factor test apply to the resolution of choice-of-law issues arising under tort law) (citing *Nodak Mut. Ins. Co. v. Am. Family Mut. Ins. Co.*, 604 N.W.2d 91, 94–96 (Minn. 2000)). With respect to the first factor, the court should look to the state with "the most significant contacts with the facts relevant to the litigation." *Id.* Here, that state is Wisconsin, where the plaintiff resides, underwent implantation surgery, and received follow-up medical care. (*See* Pl.'s Resp. in Opp. to Def.'s Mot. for Summ. J. ("Pl.'s Resp.") [Docket 80], at 1–2). The second factor, which requires the court to consider "the state law in which the plaintiff lives and in which the injury occurred," *In re Baycol*, 218 F.R.D. at 207, also weighs in favor of applying Wisconsin law. *See, e.g.*, *id.* ("[A]s the injury occurred in the state of plaintiff's residence, the substantive law of the state of plaintiff's residence should be applied to their claims."); *Foster v. St. Jude Med., Inc.*, 229 F.R.D. 599, 605 (D. Minn. 2005) ("[P]roper consideration of Minnesota's choice-of-law factors reveals that the law of the state where the [d]evice was implanted would apply to Plaintiffs' [products liability] claims.").

Having considered both factors in Minnesota's choice-of-law test, I **FIND** that Wisconsin

law governs the plaintiff's substantive claims in this case. I now turn to the merits of the pending motions.

III. Analysis

A. Defective Design

BSC moves for summary judgment on the plaintiff's strict liability for defective design claim and her negligent design claim. Beginning with strict liability, I rely on Wisconsin's codified test, newly adopted in 2011, for product liability claims. Under this regime, a manufacturer is strictly liable for a defective design where (1) the product contains a design defect; (2) the defective condition rendered the product "unreasonably dangerous"; (3) the defective condition existed at the time the product left the manufacturer's control; (4) the product reached the user without substantial changes; and (5) the defective condition caused the plaintiff's damages. Wis. Stat. § 895.047(1) (2014). A product contains a design defect "if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the manufacturer and the omission of the alternative design renders the product not reasonably safe." *Id.*

First, BSC argues that this court must dismiss the plaintiff's design defect claim because the plaintiff failed to rebut the statutory presumption set forth in Wisconsin Statute § 895.047, which states that

> [e]vidence that the product, at the time of sale, complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency shall create a rebuttable presumption that the product is not defective.

§ 895.047(3)(b). Here, the Obtryx device was cleared for marketing under the FDA's 510(k) process, thereby indicating BSC's compliance with federal standards. Accordingly, BSC contends that because the plaintiff has not shown otherwise, the Obtryx is presumptively not

defective. To analyze BSC's argument, I must ascertain how rebuttable presumptions operate under Wisconsin law. Wisconsin Statute § 903.01 provides guidance to this effect:

> Except as provided by statute, a presumption recognized at common law or created by statute, including statutory provisions that certain basic facts are prima facie evidence of other facts, imposes on the party relying on the presumption the burden of proving the basic facts, but once the basic facts are found to exist the presumption imposes on the party against whom it is directed the burden of proving that the nonexistence of the presumed fact is more probable than its existence.

§ 903.01. Applying this procedure, I can grant summary judgment based on § 895.047's presumption of non-defectiveness if (1) BSC establishes the "basic facts" triggering the presumption, namely, that the Obtryx complied with relevant standards, conditions, or specifications; and (2) the plaintiff fails to provide sufficient evidence to create a genuine issue of material fact as to whether the nonexistence of the presumption is more probable than its existence.

Here, the plaintiff has successfully presented the requisite evidence to create a genuine issue of material fact on whether the presumption of non-defectiveness exists in this case.[1] Specifically, the plaintiff has listed several alleged defects of the Obtryx and has reinforced these allegations with expert testimony. For instance, the plaintiff argues that the Obtryx is defective because it uses too much polypropylene mesh. The expert report of Dr. Donald Ostergard provides support for this claim. (*See* Ostergard Report [Docket 80-8], at 9 (stating that the "large surface area" of the polypropylene "promotes wicking of fluids and bacteria" and "provides a safe haven for bacteria which attached themselves to the mesh during the insertion process")). The plaintiff further contends that "[a]mong the worst aspects" of the Obtryx's design is that the product cannot be removed in its entirety because pieces of the polypropylene mesh will break

[1] Thus, I need not decide whether 510(k) clearance of the Obtryx qualifies as compliance with a relevant standard, condition, or specification under § 895.047.

apart and remain in the body. (*See* Pl.'s Resp. [Docket 80], at 7–8). She also supports this contention with expert testimony from Dr. Ostergard. (*See* Ostergard Report [Docket 80-8], at 10 ("[R]emoving all the mesh is extremely difficult, if not impossible, because . . . when surgeons try to uproot the mesh i[t] breaks into smaller pieces."). I **FIND** that this evidence is sufficient to create a genuine issue of material fact on whether the Obtryx is defectively designed and whether the plaintiff has rebutted the presumption that the Obtryx is not defective. Thus, summary judgment pursuant to the presumption set forth in § 895.047 is not warranted.

BSC next asserts that that the court must dismiss the design defect claim because the plaintiff failed to present evidence of a reasonable alternative design that could have reduced or avoided her injuries. *See* § 895.047(1)(a) (stating that "a product is defective in design if the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design"). Medical societies regard slings like the Obtryx as the "gold standard" for treatment of SUI, and in BSC's view, the plaintiff has not identified a reasonable alternative to this standard. (*See* BSC's Mem. of Law in Supp. of Mot. for Summ. J. ("BSC's Mem. in Supp.") [Docket 60], at 18 (citing position statements from the American Urogynecologic Society, American Urological Association, and the FDA)). The plaintiff responds that a reasonable alternative design of the Obtryx sling would incorporate mesh with larger pores. (*See* Pl.'s Resp. [Docket 80], at 8). She cites medical experts to demonstrate that the Obtryx sling's pores are too small to allow for proper tissue ingrowth. (*See id.* at 8–9 (citing the report of Dr. Ostergard)). In addition, she refers to a scientific article showing that larger pore designs—which were viable and available prior to Ms. Hall's surgery—increase tissue integration. (*See* William S. Cobb, MD, et al., *The Argument for Lightweight Polypropylene Mesh in Hernia Repair*, Surgical Innovation, Mar. 2005, at 63–69 [Docket 80-11]). I **FIND** that

this evidence creates a genuine dispute of material fact on the issue of reasonable alternative design.

Last, BSC argues that this court should grant summary judgment on the plaintiff's defective design claims that relate to polypropylene because Wisconsin law, as interpreted by BSC, provides that a plaintiff "cannot maintain a defective design claim on allegations related to the product's ingredients when that ingredient is a characteristic of the product itself." (BSC's Mem. in Supp. [Docket 60], at 14). In support of this argument, BSC points to *Godoy ex rel. Gramling v. E.I. du Pont de Nemours & Co.*, 768 N.W.2d 674 (Wis. 2009). The plaintiff in *Godoy* claimed that white lead carbonate pigment was defectively designed because it contained lead. *Id.* at 684. The Wisconsin Supreme Court dismissed the claim, finding that lead was a "characteristic ingredient" of white lead carbonate paint. *Id.* The presence of lead could not make the pigment defective because "[r]emoving lead from white lead carbonate pigment would transform it into a different product." *Id.* BSC contends that like the lead in *Godoy*, polypropylene is an inherent characteristic of polypropylene mesh slings, and therefore, the presence of polypropylene cannot make the mesh defective.

As an initial matter, it is not clear to what extent *Godoy* controls today. The court ruled on *Godoy* in 2009, two years before the enactment of Wisconsin's codified product liability law. *Godoy*, therefore, represents an application of the common law rather than an interpretation of § 895.047. This does not render *Godoy* inapplicable, however, because § 895.047 contains an affirmative defense similar to the one articulated by the *Godoy* court:

> The court shall dismiss the claimant's action under this section if the damage was caused by an *inherent characteristic* of the product that would be recognized by an ordinary person with ordinary knowledge common to the community that uses or consumes the product.

§ 895.047(3)(d) (emphasis added). Because § 895.047 does not indicate whether it replaces the common law or merely supplements it, I will interpret it in light of *Godoy*.

Unlike the plaintiff in *Godoy*, the plaintiff in this case does not argue that the mere presence of an ingredient creates a defect in the product's design. Rather, the plaintiff primarily focuses on the *amount* of the ingredient used in the design. She contends that too much polypropylene was used in the Obtryx and that by incorporating larger pores, BSC could have cut down on the amount of polypropylene used in the product. (*See* Pl.'s Resp. [Docket 80], at 9 (asserting that a better alternative design for the Obtryx "would incorporate larger pore sizes that would . . . decreas[e] the amount of polypropylene being introduced into the human body")). This distinction—between using *too much* of an ingredient and using *any* of that ingredient—matters. The latter argument can lead to dismissal, which was the case in *Godoy*. The former argument, however, can create a claim under Wisconsin law. For example,

> [i]n *Green* [*v. Smith & Nephew AHP, Inc.*, 629 N.W.2d 727 (Wis. 2001)], the plaintiff was a hospital worker who developed a severe allergy to latex. She brought suit against the manufacturer of latex gloves, alleging a defective design. Notably, the plaintiff did not claim that latex gloves were defective because they contained latex. The presence of latex is "characteristic" of latex gloves. Rather, the plaintiff alleged that they were defective because (1) they contained excessive levels of latex; and (2) they were powdered, which allowed the latex to be airborne. In effect, she argued that the quantity of latex in the gloves was not characteristic of the product, and that a particular design feature, powder, made the gloves more dangerous.

Godoy, 768 N.W.2d at 685 (internal citations omitted). The plaintiff's design defect claim in this case—which is based on excessive amounts of polypropylene—is more analogous to the allegations in *Green* than in *Godoy* and is permissible under Wisconsin law.

Even if the plaintiff had alleged that the presence of *any* polypropylene was a product defect, to achieve dismissal under § 895.047, BSC must demonstrate that there is no dispute of fact that an "ordinary person" using the Obtryx would recognize the polypropylene as a

characteristic of the product.[2] § 895.047(3)(d). BSC has failed to meet this burden. Although BSC points to several statements by the plaintiff's implanting physician, Dr. Merkitch, that indicate he understood the safety and efficacy of mid-urethral slings, (*see* Merkitch Dep. [Docket 59-9], at 17:3–25 (recounting the scientific literature he has read and the gynecological courses he attended); *id.* at 73:11–74:7 (recognizing that erosion, extrusion, and dyspareunia were risks of mid-urethral slings); *id.* at 35:14–36:9 (explaining the success rates of mid-urethral slings)), none of these statements specifically address polypropylene as an "inherent characteristic" of the Obtryx. Because BSC's proffered evidence about Dr. Merkitch's understanding of the Obtryx does not specifically relate to polypropylene, the court cannot dismiss the plaintiff's claim under the affirmative defense provided in § 895.047. *See* § 895.047 (allowing dismissal only where the "inherent characteristic . . . would be recognized by an ordinary" user of the product); *see also Ray Commc'ns, Inc. v. Clear Channel Commc'ns, Inc.*, 673 F.3d 294, 299 (4th Cir. 2012) ("Where, as here, the movant seeks summary judgment on an affirmative defense, it must conclusively establish all essential elements of that defense.").

Finding none of BSC's arguments persuasive, this court **DENIES** BSC's Motion for Summary Judgment on the strict liability for defective design claim. With respect to the negligent design claim, BSC does not raise new arguments and simply states that the negligence claim should be dismissed "for the reasons detailed" in relation to the strict liability claim. (BSC's Mem. in Supp. [Docket 60], at 18). I have already rejected these arguments, and therefore, BSC's Motion for Summary Judgment on the negligent design claim is likewise **DENIED**.

[2] The parties assume that an "ordinary" user for purposes of § 895.047 is the implanting physician. (*See* BSC's Mem. in Supp. [Docket 60], at 12 (stating that Dr. Merkitch recognized that erosion of polypropylene slings was a risk); Pl.'s Resp. [Docket 80], at 9 (stating that Dr. Merkitch did not have knowledge of the risks and dangers associated with the deformation of the Obtryx)).

B. Manufacturing Defect

BSC next moves for summary judgment on the plaintiff's manufacturing defect claim. A manufacturing defect is present when the product "departs from its intended design even though all possible care was exercised in the manufacture of the product." Wis. Stat. § 895.047(1)(a). A plaintiff must establish that a manufacturing defect "existed at the time the product left the control of the manufacturer." § 895.047(1)(c). The plaintiff argues that the Obtryx contained a manufacturing defect "as a result of its inadequate mesh pore size and propensity to degrade and deform when implanted into the human body." (Pl.'s Resp. [Docket 80], at 10). She further contends that the "composition and structure" of the Obtryx sling "did not allow the mesh to maintain its intended design as a result of degradation and deformation when used in the human body." (*Id.*). She also writes that the Obtryx sling "is produced within [BSC's] specifications and departs from [BSC's] specifications when used in a manner anticipated and directed by [BSC]." (*Id.* at 10–11). These arguments, however, relate to the product's design and behavior *after* implantation. The plaintiff points to no evidence that the Obtryx departed from its intended design at the time it left BSC's control. Accordingly, BSC's motion for summary judgment on the manufacturing defect claim is **GRANTED** and this claim is **DISMISSED**.[3]

C. Failure to Warn

BSC moves for summary judgment on the plaintiff's strict liability and negligent failure-to-warn claims, arguing that the plaintiff has failed to demonstrate that BSC's warnings were inadequate or that they caused Ms. Hall's injuries. For strict liability claims, a product is defective for want of adequate instructions or warnings "only if the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the manufacturer and the omission of the instructions or warnings

[3] There appears to be no allegation of negligent manufacturing.

renders the product not reasonably safe." Wis. Stat. § 895.047(1)(a). A plaintiff suing in strict liability must also prove that the inadequate instructions or warnings were "a cause" of the plaintiff's damages. § 895.047(1)(e).

BSC asks the court to employ the learned intermediary doctrine in its application of Wisconsin's statute on failure to warn. The learned intermediary doctrine allows a manufacturer "to fulfill its duty to warn about the known dangers arising from use of its products and avoid liability for failure to warn by adequately warning the physician," thus relieving manufacturers of prescription drugs and medical devices of the duty to warn the patients directly about the product's dangerous propensities. *Forst v. SmithKline Beecham Corp.*, 602 F. Supp. 2d 960, 968 (E.D. Wis. 2009). The reasoning behind the learned intermediary rule is that a prescribing physician—the "learned intermediary"—"is in the best position to understand the patient's needs and assess the risks and benefits of a particular course of treatment." *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984). If the court applied the learned intermediary doctrine in this case, as BSC urges me to do, BSC's liability for failure to warn would depend on whether it adequately warned the implanting physician, Dr. Merkitch, about the risks associated with the Obtryx device. Whether it directly warned the plaintiff would not matter.

The Wisconsin Supreme Court has not had the opportunity to decide whether to adopt the learned intermediary rule, *see Forst*, 602 F. Supp. 2d at 968, and federal courts applying Wisconsin law are split on the issue. Several federal courts have used the rule without mentioning that the state supreme court has not yet expressly adopted it. *See, e.g.*, *Menges v. Depuy Motech, Inc.*, 61 F. Supp. 2d 817, 830 (N.D. Ind. 1999) (citing Virginia and Georgia cases); *Lukaszewicz v. Ortho Pharm. Corp.*, 510 F. Supp. 961, 963, *amended*, 532 F. Supp. 211 (E.D. Wis. 1981) (recognizing that the learned intermediary rule is a "general rule [of] the courts

of this country"). More recent decisions by federal courts, however, reach the opposite conclusion and decline to apply the learned intermediary doctrine under Wisconsin law. *See Maynard v. Abbott Labs.*, No. 12-C-0939, 2013 WL 695817, at *5 (E.D. Wis. Feb. 26, 2013) ("Wisconsin does not apply the learned intermediary doctrine, . . ."); *Forst*, 602 F. Supp. 2d at 968 (declining to adopt the learned intermediary rule "without some indication that the state's highest court would apply the doctrine if given the opportunity to do so") (quotation marks omitted); *Peters v. AstraZeneca, LP*, 417 F. Supp. 2d 1051, 1054 (W.D. Wis. 2006) (same).

I need not resolve this issue here. Regardless of whether BSC's duty to warn extended to the implanting physician or to the plaintiff directly, the plaintiff has failed to present evidence that any inadequate warnings or instructions caused her injuries, as required under Wisconsin products liability law. *See* § 895.047(1)(e) (requiring a plaintiff to prove that "the defective condition was a cause" of her injuries). Similarly, in a suit for negligence, the plaintiff must show that the defendant's breach of duty caused her harm. *See Gritzner v. Michael R.*, 611 N.W.2d 906, 912 (Wis. 2000) (stating that plaintiffs claiming negligence must prove "a causal connection between the defendant's breach of the duty of care and the plaintiff's injury").

Assuming the learned intermediary doctrine applies to this case, the plaintiff must show that Dr. Merkitch would not have prescribed the device but for the inadequate warnings or instructions. *See, e.g.*, *Forst*, 602 F. Supp. 2d at 968 (explaining that if the learned intermediary doctrine applied, there must be evidence that the omitted warning "would have affected [the treating physician's] prescribing decision"). The plaintiff has pointed to no evidence to suggest this causal relationship. At most, she shows that Dr. Merkitch was not warned about all risks of the Obtryx. In his deposition, he stated that he did not recall being told by BSC sales representatives about the risks of erosion, extrusion, mesh stiffening, sexual dysfunction,

recurrent stress urinary incontinence, or that the sling would be difficult to remove entirely. (*See* Merkitch Dep. [Docket 80-13], at 66:6–25). But this evidence, even if it demonstrates an inadequate warning, does not relate to whether the inadequate warning caused Dr. Merkitch to prescribe the device, ultimately injuring the plaintiff. *See, e.g.*, *Menges*, 61 F. Supp. 2d at 830 ("[A] plaintiff must not only show that the manufacturer's warning was inadequate, but that such inadequacy affected the prescribing physician's use of the product and thereby injured the plaintiff.") (applying Wisconsin law).

Alternatively, assuming the learned intermediary doctrine is inapplicable in Wisconsin such that BSC had a duty to warn the plaintiff directly, the plaintiff still has not provided evidence of causation. Although she stated on her Plaintiff Fact Sheet that she "does not recall receiving any written or verbal information or instructions, including any risks or complications that might be associated with use of the Obtryx sling prior to her implantation," (Pl.'s Resp. [Docket 80], at 13 (citing Pl. Fact Sheet [Docket 59-2], at 5)), this evidence again relates to the *adequacy* of the warnings, not whether the warnings (or lack thereof) *caused* her injuries. The deposition testimony that the plaintiff refers to in her Response also fails to support causation. The vague testimony appears to indicate that the plaintiff regrets getting the Obtryx sling implant:

> Q. If you knew what you knew now with the type of injuries that you have sustained – strike that. If you knew the injuries – or strike that.
>
> With the injuries that you've sustained today, from, what, implant to removal to where you are today, would you have gone through with the surgery when you had the mesh implanted with you?
>
> A. No.

(Hall Dep. [Docket 80-3], at 250:23–251:3). While the plaintiff contends that this testimony shows that she was not advised of the risks associated with the Obtryx device, this is an

inexplicable leap of logic. This testimony has nothing to do with warnings. The plaintiff does not say that she would have declined to use the Obtryx had she received better warnings. Rather, she states that, with the knowledge of her injuries at present, she would not have undergone surgery. This is not sufficient to demonstrate the causation required to maintain a failure-to-warn claim.

For these reasons, I **FIND** that the plaintiff has failed to present evidence in support of her strict liability and negligent failure-to-warn claims. Accordingly, BSC's motion for summary judgment is **GRANTED** on these claims, and these claims are **DISMISSED**.[4]

D. Express and Implied Warranties and Fraudulent Concealment

The plaintiff has expressly withdrawn her claims for breach of express and implied warranties. (*See* Pl.'s Resp. [Docket 80], at 1 n.1). In addition, the plaintiff has not opposed summary judgment on her fraudulent concealment claim. Accordingly, BSC's motion for summary judgment on breach of express warranty, breach of implied warranty, and fraudulent concealment is **GRANTED**, and these claims are **DISMISSED**.

E. Preemption Defenses

BSC asserts two preemption-based affirmative defenses: express preemption and implied preemption by the Federal Food, Drug, and Cosmetic Act ("FDCA"). The plaintiff moves for summary judgment on these affirmative defenses on the basis that her state law claims are not barred by federal preemption. I have repeatedly addressed preemption issues throughout these MDLs, and I have consistently found that federal preemption does not apply. *See, e.g.*, *Huskey v. Ethicon, Inc.*, No. 2:12-cv-05201, 2014 WL 3362287, at *8–14 (S.D. W. Va. July 8, 2014); *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361920, at *3–9 (S.D. W. Va. July 8, 2014); *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 756–61 (S.D. W. Va. 2014); *In re C.*

[4] Because the failure-to-warn claim is dismissed, I need not resolve the plaintiff's motion for summary judgment on BSC's use of the learned intermediary doctrine as an affirmative defense. Accordingly, that motion is **DENIED as moot**.

R. Bard, Inc., No. 2:10-cv-01224, 2013 WL 2431975, at *11 (S.D. W. Va. June 4, 2013). Here, too, preemption is not available to BSC.

In interpreting the express preemption provision of the Medical Device Amendments to the FDCA, the Supreme Court has foreclosed the possibility of an express preemption defense in this case. The provision provides that, with respect to medical devices, state law may not impose any requirement "which is different from, or in addition to" the requirements of the FDCA, or any requirement "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the FDCA]." 21 U.S.C. § 360k(a) (2012). The Supreme Court concluded that because the 510(k) clearance requirements do not relate to the safety or efficacy of the device, the FDCA does not preempt products liability claims regarding medical devices that underwent 510(k) clearance rather than the premarket approval process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 501–02 (1996). As the Court noted,

> [t]he generality of [the 510(k)] requirements make this quite unlike a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. Rather, the federal requirements reflect important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements.

Id. at 501. The Obtryx device was cleared through the 510(k) process. (BSC's Mem. in Supp. [Docket 60], at 10 (citing to the FDA's "510k Clearance Letter" for the Obtryx)). Therefore, BSC's express preemption defense must fail.[5]

BSC's affirmative defense of implied preemption suffers the same fate. Although the FDCA impliedly preempts private claims that seek to enforce FDCA provisions against a

[5] For an explanation of the FDA's 510(k) clearance process and further discussion of *Lohr*, see *Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 751–52 (S.D. W. Va. 2014).

manufacturer, *see* 21 U.S.C. § 337(a) ("[A]ll such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."); *Buckman Co. v. Pl.'s Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions[.]"), the plaintiff has confirmed that she does not assert any claims that BSC violated the FDCA or committed fraud on the FDA. (*See* Pl.'s Mem. in Supp. of Pl.'s Mot. for Partial Summ. J. [Docket 61], at 7). BSC nevertheless contends that the plaintiff will introduce evidence that BSC failed to comply with the FDCA by (1) mislabeling the Obtryx and (2) failing to report adverse product events to the FDA. BSC thus argues it is entitled to assert the implied preemption defense.

BSC's fears are unfounded. As I have repeatedly ruled, and as I now hold in this case, no party will be permitted to introduce evidence relating to the FDA or the 510(k) clearance process. *See, e.g.*, *Lewis*, 991 F. Supp. 2d at 754–56; *In re C. R. Bard, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, MDL 2187, 2013 WL 3282926, at *2 (S.D. W. Va. June 27, 2013). In *Lewis*, I explained that

> [e]vidence regarding the 510(k) process poses a substantial risk of misleading the jury and confusing the issues. That a device has been given clearance through the FDA's 510(k) process is not relevant to state tort law. Admission of any evidence regarding the 510(k) process runs the risk of misleading the jury to believe that FDA 510(k) clearance might be dispositive of the plaintiffs' state law claims. The prejudicial value of evidence regarding the 510(k) process far outweighs its probative value.

991 F. Supp. 2d at 754. Because the plaintiff cannot introduce FDA evidence, the implicit preemption defense is not applicable. Accordingly, the plaintiff's motion for summary judgment on BSC's preemption defenses is **GRANTED**.

IV. Conclusion

For the reasons state above, BSC's Motion for Summary Judgment [Docket 59] is **GRANTED in part** and **DENIED in part**, and the plaintiff's Motion for Partial Summary Judgment [Docket 61] is **GRANTED in part** and **DENIED as moot in part**.

The court **DIRECTS** the Clerk to send a copy of this Order to counsel of record and any unrepresented party.

ENTER: February 27, 2015

JOSEPH R. GOODWIN
UNITED STATES DISTRICT JUDGE